DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2005

Ostar Meditech Corporation
c/o Mr. Steven Chang
5F, No. 46-4, Min Chiuan Road
Shing -Tien City
Taipei Hsien, CHINA 231

Re: K050680
Trade Name: Blood Pressure Monitor with Spectrum/P2, X2, A2 and K7
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: March 14,2005
Received: March 16,2005

Dear Mr. Chang:

This letter corrects our substantially equivalent letter of May 13,2005, regarding the contact's name and address.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MAY 13 2005

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K050680

1. Submitter's Identifications:
   Ostar Technology Corp.
   5F, No. 46-4, Min-Chiuan Rd., Shing-Tien City,
   Taipei Hsien 231, Taiwan, R.O.C.

   Contact:
   Mr. Steven Chang
   President

   Date of Summary Preparation: February 25, 2005.

2. Name of the Device:
   Blood Pressure Monitor with Spectrum /Models P2, X2, A2 and K7..

3. Information of the 510(k) Cleared Device (Predicate Device):
   DynaPulse 500G, (k number : K012498).

4. Device Description:

   Basically the measuring system were composite of blood pressure measuring circuit via Oscillometric method, pressure sensor, measuring cuff at arm, pneumatic pump, inflation and deflation system, housing, display LCD, and measuring software...and so on.

   The main operation for the blood pressure measurement is carried out in such a way that the measuring cuff at arm is inflated to the estimated pressure level, then deflated to zero automatically. During the inflation and deflation, the pressure change with respective of time were recorded as the data base of measurement. Then the following measuring results will be calculated against the measurement data base :
   - Blood pressure information including systolic and diastolic pressure (calculated via Oscillometric method)
   - Heart beat rate.
   - Heart beat noise calculated via FFT (Fast Fourier Transformation).

   For the display of measuring results and operation interface, the following difference were provided for the following different models :
   - For model K7, the personal computer model PX-31X-46-XXX/FLYTECH was integrated with the whole measurement system so as to provide the operation interface and display of measuring results including pressure waveform, noise waveform, systolic and diastolic pressure, heat beat rate, and noise index.
   - For model A2, RS 232 is provided for the connection with PC for the measurement operation and display of measurement results. The operation and display details are completely identical to that of model K7.

- For model X2 and P2, all the measurement components are mounted within a compact housing with operation key and display LCD. These two models do not display the measurement waveform and noise waveform, but they could display the measurement results of systolic and diastolic pressure, heat beat rate, and noise index.

In general the models A2 and K7 are the device used by trained medical professionals to operate on patient at clinical setting to collect and measure blood pressure. Whilst the two models X2 and P2 , are indicated for patients at home who are capable and willing to self-administrate this device for the blood pressure monitor upon prescription of their healthcare provider.

5. Intended Use:

The Ostar A2, and K7 are indicated for trained medical professionals to operate on patient at clinical settings to collect and measure blood pressure, pulse rate noise index and pressure waveform diagram (including heartbeat waveform and noise waveform). In addition, the Ostar P2 and X2 are indicated for patients at home who are capable and willing to self-administrate this device upon prescription of their healthcare provider. P2 and X2 do not display the measuring waveform.

The devices do not send any real-time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The cleared device for the specification comparison of A2,K7,X2, and P2 is DynaPulse 500G (K012498).

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, SP 10-1992, as well as EN 60601-1, and EN 60601-1-2 requirement.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

8. Conclusions

The Ostar Blood Pressure Monitor with Spectrum and/or Index, including model A2, K7, X2, and P2, have the same intended use and technological characteristics as the cleared device of DynaPulse model 500G. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Indications For Use

510(k) Number (if known): K050680

Device Name: Blood Pressure Monitor with Spectrum/P2, X2, A2 and K7.

Indications For Use:

The Ostar A2, and K7 are indicated for trained medical professionals to operate on patient at clinical settings to collect and measure blood pressure, pulse rate noise index and pressure waveform diagram (including heartbeat waveform and noise waveform). In addition, the Ostar P2 and X2 are indicated for patients at home who are capable and willing to self-administrate this device upon prescription of their healthcare provider P2 and X2 do not display the measuring waveform.

The devices do not send any real-time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

Prescription Use __√__ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050680

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